had a very friendly conversation—as we often do.

I talked to her about my father, who had likewise died from cancer. He was a medical doctor who devoted his life to others. We engaged briefly in a conversation.

I said: It took great courage for you not to seek the Lieutenant Governor's post.

She acknowledged that, and then, with a twinkle in her eye—she was a very attractive woman, by the way—she said: Yes. I thought about the Lieutenant Governor post because that was going to be a way stop to come and have a campaign against you, Senator WARNER.

And she could have waged a campaign against this old Senator that would give him a wakeup call, for sure.

Our State has lost one of its shining stars, but that is God's will, and we must accept it. I share with the Senator our prayers for her family and her friends.

Mr. ALLEN. Thank you, Madam President.

The PRESIDING OFFICER. The Senator from Connecticut.

Mr. DODD. Madam President, I add my voice to that of the two Senators from Virginia. I did not know Emily Couric, but having listened to the distinguished junior Senator from Virginia speak about her, and the senior Senator, not only did Virginia lose someone of great value but the country did as well. I am sure her family and friends appreciate immensely the words spoken in this Chamber this afternoon. I am sure all of us would like to associate ourselves with them. We express our sympathies to them.

BEST PHARMACEUTICALS FOR CHILDREN ACT

Mr. DODD. Madam President, I ask unanimous consent that the Senate now proceed to the consideration of Calendar No. 184, S. 838; that the only amendment in order other than the committee-reported substitute be a Dodd-DeWine amendment; that the amendment be agreed to, the committee substitute, as amended, be agreed to, the bill, as amended, be read three times, passed, and the motion to reconsider be laid upon the table, with the above occurring with no intervening action or debate.

The PRESIDING OFFICER. Without objection, it is so ordered.

The Senate proceeded to consider the bill (S. 838) to amend the Federal Food, Drug, and Cosmetic Act to improve the safety and efficacy of pharmaceuticals for children, which had been reported from the Committee on Health, Education, Labor, and Pensions, with an amendment to strike all after the enacting clause and inserting in lieu thereof the following:

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Best Pharmaceuticals for Children Act''.

SEC. 2. PEDIATRIC STUDIES OF ALREADY-MARKETED DRUGS.

Section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a) is amended—

(1) by striking subsection (b); and

(2) in subsection (c)—

(A) by inserting after ''the Secretary'' the following: ''determines that information relating to the use of an approved drug in the pediatric population may produce health benefits in that population and''; and

(B) by striking ''concerning a drug identified in the list described in subsection (b)''.

SEC. 3. RESEARCH FUND FOR THE STUDY OF DRUGS LACKING EXCLUSIVITY.

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended—

(1) by redesignating the second section 409C, relating to clinical research (42 U.S.C. 284k), as section 409G;

(2) by redesignating the second section 409D, relating to enhancement awards (42 U.S.C. 284l), as section 409H; and

(3) by adding at the end the following:

''SEC. 409I. PROGRAM FOR PEDIATRIC STUDIES OF DRUGS LACKING EXCLUSIVITY.

''(a) LIST OF DRUGS LACKING EXCLUSIVITY FOR WHICH PEDIATRIC STUDIES ARE NEEDED.—

''(1) IN GENERAL.—Not later than 1 year after the date of enactment of this section, the Secretary, acting through the Director of the National Institutes of Health and in consultation with the Commissioner of Food and Drugs and experts in pediatric research, shall develop, prioritize, and publish an annual list of approved drugs for which—

''(A)(i) there is an approved application under section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j));

''(ii) there is a submitted application that could be approved under the criteria of section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)); or

''(iii) there is no patent protection or market exclusivity protection under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

''(B) additional studies are needed to assess the safety and effectiveness of the use of the drug in the pediatric population.

''(2) CONSIDERATION OF AVAILABLE INFORMATION.—In developing the list under paragraph (1), the Secretary shall consider, for each drug on the list—

''(A) the availability of information concerning the safe and effective use of the drug in the pediatric population;

''(B) whether additional information is needed;

''(C) whether new pediatric studies concerning the drug may produce health benefits in the pediatric population; and

''(D) whether reformulation of the drug is necessary;

''(b) CONTRACTS FOR PEDIATRIC STUDIES.—The Secretary shall award contracts to entities that have the expertise to conduct pediatric clinical trials (including qualified universities, hospitals, laboratories, contract research organizations, federally funded programs such as pediatric pharmacology research units, other public or private institutions, or individuals) to enable the entities to conduct pediatric studies concerning one or more drugs identified in the list described in subsection (a).

''(c) PROCESS FOR CONTRACTS AND LABELING CHANGES.—

''(1) WRITTEN REQUEST TO HOLDERS OF APPROVED APPLICATIONS FOR DRUGS LACKING EXCLUSIVITY.—

''(A) IN GENERAL.—The Commissioner of Food and Drugs, in consultation with the Director of National Institutes of Health, may issue a written request (which shall include a timeframe for negotiations for an agreement) for pediatric studies concerning a drug identified in the list described in subsection (a) to all holders of an approved application for the drug under section 505 of the Federal Food, Drug, and Cosmetic Act. Such a request shall be made in accordance with section 505A of the Federal Food, Drug, and Cosmetic Act.

''(B) PUBLICATION OF REQUEST.—If the Commissioner of Food and Drugs does not receive a response to a written request issued under subparagraph (A) within 30 days of the date on which a request was issued, the Secretary, acting through the Director of National Institutes of Health and in consultation with the Commissioner of Food and Drugs, shall publish a request for contract proposals to conduct the pediatric studies described in the written request.

''(C) DISQUALIFICATION.—A holder that receives a first right of refusal shall not be entitled to respond to a request for contract proposals under subparagraph (B).

''(D) GUIDANCE.—Not later than 270 days after the date of enactment of this section, the Commissioner of Food and Drugs shall promulgate guidance to establish the process for the submission of responses to written requests under subparagraph (A).

''(2) CONTRACTS.—A contract under this section may be awarded only if a proposal for the contract is submitted to the Secretary in such form and manner, and containing such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

''(3) REPORTING OF STUDIES.—

''(A) Upon completion of a pediatric study in accordance with a contract awarded under this section, a report concerning the study shall be submitted to the Director of National Institutes of Health and the Commissioner of Food and Drugs. The report shall include all data generated in connection with the study.

''(B) AVAILABILITY OF REPORTS.—Each report submitted under subparagraph (A) shall be considered to be in the public domain, and shall be assigned a docket number by the Commissioner of Food and Drugs. An interested person may submit written comments concerning such pediatric studies to the Commissioner of Food and Drugs, and the written comments shall become part of the docket file with respect to each of the drugs.

''(C) ACTION BY COMMISSIONER.—The Commissioner of Food and Drugs shall take appropriate action in response to the reports submitted under subparagraph (A) in accordance with paragraph (4).

''(4) REQUEST FOR LABELING CHANGES.—During the 180-day period after the date on which a report is submitted under paragraph (3)(A), the Commissioner of Food and Drugs shall—

''(A) review the report and such other data as are available concerning the safe and effective use in the pediatric population of the drug studied; and

''(B) negotiate with the holders of approved applications for the drug studied for any labeling changes that the Commissioner of Food and Drugs determines to be appropriate and requests the holders to make; and

''(C)(i) place in the public docket file a copy of the report and of any requested labeling changes; and

''(ii) publish in the Federal Register a summary of the report and a copy of any requested labeling changes.

''(5) DISPUTE RESOLUTION.—If, not later than the end of the 180-day period specified in paragraph (4), the holder of an approved application for the drug involved does not agree to any labeling change requested by the Commissioner of Food and Drugs under that paragraph—

''(A) the Commissioner of Food and Drugs shall immediately refer the request to the Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee; and

''(B) not later than 90 days after receiving the referral, the Subcommittee shall—

''(i) review the available information on the safe and effective use of the drug in the pediatric population, including study reports submitted under this section; and